



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Handwritten signature/initials

OCT 5 1988

Re: Novantrone
Docket No. 88E-0067

SOLICITOR

OCT 12 1988

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, DC 20231

U.S. PATENT & TRADEMARK OFFICE

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,278,689 filed by the American Cyanamid Co. under 35 U.S.C. 156. The patent claims the human drug product named Novantrone (mitoxantrone hydrochloride), New Drug Application number 19-297.

In the March 30, 1988 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before September 26, 1988, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156 (d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice regarding Novantrone has expired, and FDA has received no such petition. FDA, therefore, considers Novantrone's regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Handwritten signature of Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Alphonse R. Noe, Manager
Patent Law Department
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